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October 15, 2001

Robert L. Stephenson II, M.P.H.
Director, Division of Workplace Programs
CSAP
5600 Fishers Lane
Rockwall II, Suite 815
Rockville, MD 20857

Dear Mr. Stephenson:

This letter is written in response to the Notice of proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs published August 21, 2001. Overall the proposed revisions appear to help bring some order to the area of Validity Testing. This has been a problematic and confusing topic for several years.

The most significant comment I have is that these revisions must be reflected in the Department of Transportation 49 CFR Part 40 regulations as well. The new DOT regulations are at odds with the proposed changes in many points. Cutoffs for creatinine, specific gravity, and pH need to be the same for both programs.

The HHS proposal requires certain validity tests for all primary specimens (creatinine, specific gravity (as needed), pH and oxidizing adulterants), and allows additional testing when circumstances indicate. DOT regulations require that each primary specimen be tested for **all** adulterants for which HHS has given direction or guidance. It needs to be clear to each lab what adulterants to check in **all** primary specimens and what other adulterants the lab must be able to measure.

Guidance on how to handle unidentified interferences also needs to be the same between DOT and HHS. DOT specifies that a specimen with an unidentified interference **must** be sent to another HHS lab able to identify it. It does not specify any means of knowing what test, or panel of tests to order, nor is there a way for one HHS lab to know what tests are performed by a competitor. Also unclear is who pays the additional cost and what would happen if Lab #2 was unable to identify the interference – send to Lab #3? The HHS proposal would allow the primary lab to report a specimen with an unidentified interference as Invalid and leave the decision of whether to send to another lab up to the MRO.

Please clarify the units for Chromate (Chromium VI). An LOD of 20 ug/mL of chromate (chromium VI) is specified for the general oxidant test. Is this 20 ug/mL of the oxidant species Chromate - $CrO_4^{=}$ (formula weight 116) - or is it 20 ug/mL of Chromium (VI) - Cr (VI) –

(formula weight 52)? This is significant since there is a difference of more than a factor of two in the measured LOD depending on which units are correct.

The proposal should also contain language that more fully addresses the issue of the dynamic nature of the adulterant industry. The UrineLuck website, for example, now claims that the formula changes every 6-9 months and that it no longer contains nitrite, chromate or pyridine. HHS must continue to recognize the need for flexibility to adapt to the new adulterants (and eliminate old ones), in close to real time, while maintaining a forensically defensible testing system.

Along that line, is it possible to add to the regulations a prohibition against the manufacture and sale of products advertised or sold as adulterants? There are dozens of sites on the Internet selling these products, some of which are quite sophisticated. The products are clearly marketed to defeat drug testing programs including (especially) the federal programs. The following is a quote from the UrineLuck website (emphasis mine):

> "DOT tests are the hardest test to pass if the donor does not use a detoxifying product. **However, if a detoxifying product is used, the DOT is the easiest test pass**. Each type of detoxifying product works via a unique mechanism on drug tests. Refer to the product sections of this report for the mechanism information and explanation. Guidelines for the DOT test procedures, reporting, and adulteration, can be found on the Department of Health and Human Services or the Department of Transportation web page at www.dot.gov/ost/dapc/guidelines/Urine.htm."

With minor modification the proposed changes should make an improvement in the quality and standardization of validity testing.

Sincerely,

Gregory L. Randall, C(ASCP)
Technical Supervisor
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